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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,396	08/17/2006	Irene Corthesy-Theulaz	112701-722	8622

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
10/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/595,396	CORTHESY-THEULAZ ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-19* is/are pending in the application.

4a) Of the above claim(s) *12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11-28-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Claims 1-3, 5-19 are pending. Applicant's election of Group I drawn to a yeast extract used to manufacture an oral composition, i.e., claims 1-3 and 5-11 in Applicant's reply filed on 07-21-2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, Claims 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention, there being no allowable generic or linking claim.

Therefore, claims 1-3 and 5-11 are currently under examination to which the following grounds of rejection are applicable.

Information Disclosure Statement

1. The information disclosure statements filed on November 28, 2006 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copies.

2. The information disclosure statement filed on November 28, 2006 fails to comply with 37 C.F.R. § 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The following reference has not been considered Chapoy P. (1985, *Actualite therapeutique,* pp. 562-563) as an English translation of the Chapoy P. publication has not been provided.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 5-11 are rejected under 35 U.S.C. 101 for being directed to non-statutory subject matter. The claims recitation of use is non-statutory. The MPEP 2173.05(q) under the heading "Use" Claims recites,

> Other decisions suggest that a more appropriate basis for this type of rejection is 35 U.S.C. 101. In Ex parte Dunki, 153 USPQ 678 (Bd. App. 1967), the Board held the following claim to be an improper definition of a process: "The use of a high carbon austenitic iron alloy having a proportion of free carbon as a vehicle brake part subject to stress by sliding friction." In Clinical Products Ltd. v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966), the district court held the following claim was definite, but that it was not a proper process claim under 35 U.S.C. 101: "The use of a sustained release therapeutic agent in the body of ephedrine absorbed upon polystyrene sulfonic acid." Although a claim should be interpreted in light of the specification disclosure, it is generally considered improper to read limitations contained in the specification into the claims. See In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and In re Winkhaus, 527 F.2d 637, 188 USPQ 129 (CCPA 1975), which discuss the premise that one cannot rely on the specification to impart limitations to the claim that are not recited in the claim.

The claims should be redrafted such that they particularly point out the components and, where necessary, the absolute amounts thereof within the composition.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language.

Claim 1 is vague and indefinite in its recitation of "use of a yeast extract" in that the metes and bounds of the term " use of a yeast extract " are unclear. Likewise, 2-3 and 5-11, depending on claim 1, are vague and indefinite in their recitation of "The use of claim 1" in that the metes and bounds of the phrase "The use of claim 1" are unclear. It is unclear whether claims 1-3 and 5-11 are methods or products claims. Applicant appears to be attempting to claim both a composition and a use thereof, which is non-statutory. The claims should be redrafted such that they particularly point out the components and, where necessary, the absolute amounts thereof within the composition. As such, the metes and bounds of the claims cannot be determined.

For the purpose of a compact prosecution claims 1-3 and 5-11 are interpreted as product claims as reflected in the restriction requirement mailed on May 194, 2008 and applicants' election of Group I in the response filed on 07-21-2008.

Claim Rejections - 35 USC § 102

The following is a quotation of 35 U.S.C. 102(b) which forms the basis for all obviousness rejections set forth in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 3 are rejected under 435 U.S.C. 102(b) as being anticipated by Tomohiko a et al., JP 2001055338 A (Date of publication February 27, 2001. A machine generated

translation is provided. An official translation of the document has been requested) as evidence by Mims et al., (Medical Microbiology, 3rd edition, 2004, pp. 277-289).

Tomohiko et al. teaches pharmacological compositions comprising yeast extract, e.g., a yeast cell wall fraction for treatment of diseases including diarrhea (paragraphs [0008] [0012] [0031) (Current claims **1, 2 and 3**).

Though Tomohiko et al., does not explicitly teach that diarrhea is caused by enterotoxin-producing pathogens such as *Clostridium, E. coli, Salmonella, Vibrio* and other bacteria, diarrheal diseases are caused by enterotoxin-producing by bacteria as evidence by the teachings of Mims et al.,. Thus diarrheal diseases are in inherently caused by enterotoxin- producing pathogens.

Absent evidence to the contrary, the composition disclosed in Tomohiko et al., has all of the properties cited in the claims.

Claim Rejections - 35 USC § 103

The phrase "meat extract" is defined in the specification as a chemical able to provide amino acids (Specification, p. 2, lines 32). Note that the specification does not disclose a definition of the term "adjuvant", accordingly, the term "adjuvant" is broadly interpreted as any composition facilitating delivery of a medication (e.g., water, buffer).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomohiko a et al., JP 2001055338 A (Date of publication February 27, 2001, A machine generated translation is provided. An official translation of the document has been requested), in view of Pei et al., (US publication No. 2005/0244392; Date of Publication Nov. 3, 2005).

Tomohiko et al. teaches pharmacological compositions comprising yeast extract, e.g., a yeast cell wall fraction for treatment of diseases including diarrhea (paragraphs [0008] [0012] [0031]) (**Current claim 1**).

Tomohiko et al. does not specifically teach oral compositions comprising peptones and meat extracts.

However, at the time the invention was made, Pei et al., discloses probiotic compositions used for prophylaxis or treatment against digestive diseases including diarrhea (p. 1, paragraph [0006]; p. 6, paragraph [0085]). Moreover, Pei et al., teaches that the probiotic composition can be prepared as an infant formula comprising denatured whey proteins (p. 18, paragraph [0167]; p. 19, paragraph [0170] (**Current claims 5, 6, 9 and 10**), milk fat, proteins and fermented based fermented products (page 5, paragraph [0074]; page 19, paragraph [0168]) (**Current claims 7 and 11**). Note that proteins of animal origin are interpreted as meat extracts. Furthermore, Pei et al., teaches pharmaceutically acceptable excipients (p.5, paragraph [0076][0077]) (**Current claim 8**).

Therefore, it would have been *prima facie* obvious for the skilled artisan to modify the yeast extract taught by Tomohiko et al., to improve the efficacy of the therapeutic response in the

host by mixing the yeast extract with denatured whey proteins and other animal derived proteins as taught by Pei et al., in an infant formula preparation. The manipulation of previously identified probiotic components and formulation of compositions is within the ordinary level of skill in the art. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success in modifying the yeast composition against diarrhea caused by enterotoxin-producing pathogens with the formulation disclosed by Pei et al. by combining the disclosures of Tomohiko and Pei, particularly because both teach compositions to ameliorate digestive diseases, including diarrhea. Furthermore, Pei et al., does not teach all of the claimed reagents concentrations, however, the Pei, et al., clearly recognizes that the concentration of reagents including peptones and meat extract (e.g., proteins) is a result effective variable. At the time the invention was made it would have been obvious to optimize these result effective variables therefore the claimed invention would have been obvious. Generally, differences in experimental parameters such as concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such parameter is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.");< ** In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there

was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

One of ordinary skill in the art would have had a reasonable expectation of success in generating a yeast extract comprising whey protein and meat extract in an oral composition to treat the effects of infection caused by enterotoxin-producing pathogens as evidenced by the production of said compositions in the instant specification by following the combined teachings of Tomohiko and Pei.

Provisional Rejection, Obviousness Type Double Patenting - No Secondary Reference(s)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/595,397. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants.

For example, claim 1 of copending Application No. 10/595,397, is drawn to an oral composition comprising peptones and/or meat extracts to treat the effects of infection by enterotoxin-producing pathogens, claim 8 further limits the composition to the addition of yeast extracts.

Claim 1 of the instant invention is drawn to an oral composition to treat the effects of infection by enterotoxin-producing pathogens, and claim 5 and further limits the composition of claim 1 to having peptones and meat extracts, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-3 and 5-11 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any

inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, PhD
Examiner, Art Unit 1633